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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/569,798

11/14/2006

Vic Young

5331-105

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23117 7590 09/30/2009
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EXAMINER

YOUNG, MICAH PAUL

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

09/30/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-----------------------------------|--|
| Office Action Summary | Application No. 10/569,798 | Applicant(s) YOUNG, VIC | |
| | Examiner MICAH-PAUL YOUNG | Art Unit 1618 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/27/06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 2/27/06 was filed in a timely manner. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-12, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Scholl (USPN 3,350,329 hereafter '329) as evidenced by Vasington et al (USPN 4,778,749 hereafter '749).

The '329 patent teaches an coating composition comprising an aqueous alkali shellac solution and sodium alginate (Example 2). The formulation comprises 30-35% shellac and a nearly equivalent amount of sodium alginate (Example 2, claims). The sodium alginate is a low viscosity thickening agent that is added to adjust the viscosity of the formulation from 20-1000 cps (col. 3, lin. 70-col. 4, lin. 13). The formulation further includes polyethylene glycol a known plasticizer (Example 5). The coating is prepared by mixing the aqueous alkali shellac and sodium alginate together (Example 2). The coating composition is in liquid form with solids content meaning the composition is a suspension of particles (Example 2). The sodium alginate of the coating formulation would have a viscosity of 250 cps as evidenced by the '749 patent. A 2%

Art Unit: 1618

solution of sodium alginate has a viscosity of 250 cps (claim 1). Regarding the edible limitation, there is nothing in the coating formulation that is harmful to human consumption and as such the coating would be edible. These disclosures render the claims anticipated.

Claims 1, 2, 5, and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al (USPN 6,365,148 hereafter '148).

The '148 patent teaches an enteric coated dosage form comprising sodium alginate and shellac (abstract, col. 3, lin. 11-20, col. 3, lin. 60-65). The dosage form is spray coated with the coating formulation (Example 1). The coating formulation comprises a plasticizer (col. 4, lin. 25-33). These disclosures render the claims anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1618

Claims 1 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Scholl (USPN 3,350,329 hereafter '329).

As discussed above the '329 patent discloses a coating formulation comprising an aqueous alkali shellac compound and an alginate. The reference discloses the shellac and alginate in comparable parts by weight, with shellac present in 65 parts by weight and sodium alginate present in 60 parts by weight. It would have been obvious to optimize the concentrations of each component in order to modify the viscosity of the coating, and affecting the thickness of the coating and ease of application. A more viscous coating would provide a more stable coating with reduced cracking, while a less viscous solution would spray easier during processing. Either choice would have been an obvious modification resulting from routine experimentation by an artisan of ordinary skill.

The general conditions of the claims have been met by the prior art. The '329 patent discloses a coating formulation comprising sodium alginate, and an alkali shellac solution in comparable concentrations. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various pharmaceutical compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

Art Unit: 1618

One of ordinary skill in the art would have been motivated to modify the concentrations of the alginate and shellac components in order to optimize the viscosity of the coating solution. It would have been obvious to optimize the components with an expected result of a stable coating formulation with optimized stability, and application time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618
/MICAH-PAUL YOUNG/

Application/Control Number: 10/569,798

Page 6

Art Unit: 1618

Examiner, Art Unit 1618